

REMARKS:

In the Office Action dated September 29, 2003, claims 12 and 17 were rejected under 35 U.S.C. §112, second paragraph as being indefinite because the Examiner stated the term "metallic tubular sleeve" in claim 12 was 5 unclear, and the term "peripheral groove" in claim 17 was unclear, because the Examiner was unable to find either of those terms in the specification.

Claim 12 is directed to the embodiment shown in Figures 3-5, and the metallic tubular sleeve set forth in claim 12 was intended to refer to the element 27 shown in Figures 3 and 4. That element, however, was referred 10 to in the original text as a contact ring, and therefore the specification has been editorially amended to refer to that element as a contact sleeve. This also is helpful for distinguishing the embodiment of Figures 3-5 from the embodiment of Figure 6, wherein structure more appropriately described as contact rings is used.

15 The peripheral groove set forth in claim 17 refers to one or both of the grooves 130 and 131 shown in the embodiment of Figure 6. The paragraph in the substitute specification bridging pages 10 and 11 used reference numerals 130 and 131 initially to refer to the respective central parts of the interior of each of the contact rings, however, this paragraph has been 20 editorially amended to use those reference numerals to refer to the two inner circumferential grooves that are formed by the aforementioned central parts being free of ceramic material. It is noted that the paragraph beginning at page 11, line 13 of the substitute specification already used reference numerals 130 and 131 to refer to these grooves.

25 Lastly, the Examiner noted that the claim designated claim 18 in Amendment "A" had been incorrectly numbered, and the Examiner has renumbered that claim as claim 17.

In view of the above, all claims of the application are submitted to be in full compliance with all provisions of §112, second paragraph.

30 Additionally, the drawings were objected to because the Examiner stated reference numeral 5 shown in Figure 1 and reference numeral 122 shown in Figure 6 were not found in the specification.

In response, the paragraph beginning at page 5, line 2 has been amended to use the reference numeral 5 to designate the lock screw, and the paragraph beginning at page 10, line 15 has been amended to refer to the opposite ends 122 and 123 of the tube 121. In view of these editorial changes in the specification, no change in the drawings is necessary.

5 Additionally, a number of typographical errors were noted in the substitute specification, all of which have been corrected.

The Examiner stated that European Application 0 261 582, that was provided in the Information Disclosure Statement filed April 2, 2001 did not

10 comply with 37 C.F.R. § 1.98(a)(3) because a concise explanation of the relevance of that reference was not provided. Applicants respectfully submit that the relevancy of European Application 0 261 582 was adequately discussed in the Information Disclosure Statement so as to comply with 37 C.F.R. § 1.98(a)(3). In the second paragraph below the heading Explanation
15 of Relevance on page 2 of the Information Disclosure Statement, Reference AL was explicitly cited as being among the references that were cited during earlier examination of the present PCT application. The International Search Report in which Reference AL and those other references were cited was attached to the published PCT application that was filed as a part of the
20 original application papers. European Application 0 260 582, like the other references, is identified in the International Search Report as being in Category "A", constituting general technological background information. Applicants submit that merely the previous citation of a reference in the International Search Report in one of the designated categories is sufficient to
25 satisfy the requirements of 37 C.F.R. § 1.98(a)(3), and the aforementioned statement in the Information Disclosure Statement is sufficient to flag this relevancy. Another Form 1449 is therefore submitted herewith, wherein Reference AL is included by itself, and the Examiner is requested to initial this further Form 1449 to indicate that Reference AL has been considered and is
30 officially of record.

Claim 10 was rejected under 35 U.S.C. §102(e) as being anticipated by Johansson et al. The Examiner stated this rejection might be overcome by a

showing under 37 C.F.R. § 1.132 or 37 C.F.R. § 1.131, however, Applicants submit that the Johansson et al. reference is not available as prior art against the subject matter of this application, and therefore no rejection of any claim of the present application under 35 U.S.C. §102(e) should have been made
5 based on the Johansson et al. reference.

This is because the Johansson et al. reference has an effective date for prior art purposes as of its United States filing date, which is August 16, 1999. The present PCT application is not only entitled to the benefit of the PCT filing date, but also claims the benefit of priority based on Swedish
10 Application 9803693-2, filed in Sweden on October 27, 1998. A certified copy of the priority document was filed with the original application papers, and the Examiner acknowledged receipt of that certified copy in the Office Action summary. Since that application is in English, it is not necessary to file a certified translation in order to perfect the claim for priority, and therefore all
15 requirements to rely on the Swedish filing date have been satisfied. Since the Swedish filing date precedes the effective date for prior art purposes of the Johansson et al. reference, the Johansson et al. reference is not available as prior art against any claim of the present application.

Claim 10 also was rejected under 35 U.S.C. §103(a) as being
20 unpatentable over Schiff in view of Hawkins et al. The Examiner acknowledged that the Schiff reference does not disclose that the housing is metallic. The Examiner relied on the Hawkins et al. reference as teaching an implantable device component assembly having a metallic housing with a barrel for receiving a connector that is welded or bonded to the housing, in
25 order to secure the barrel assembly in the device. The Examiner stated it would have been obvious to a person of ordinary skill in the art to use a metallic housing and bonding or welding in the Schiff system, in order to simplify the device housing by replacing the cast epoxy connector with a metallic housing, and using a weld bond to provide firm attachment of the
30 barrel.

This rejection is respectfully traversed for the following reasons.

As discussed in the present specification, conventionally the so-called "header" or electrode lead-receiving portion of an implantable stimulation device has been made of plastic or silicone, with metallic components embedded therein and electrical connections between those metallic 5 components and the circuitry contained in the metallic portion of the stimulator housing. The stimulator disclosed in the Schiff reference is an example of such a conventional arrangement.

As also discussed in the present specification, it is known to make the stimulator housing completely of metal, however, conventionally this has 10 proven to be the exception rather than the rule, because of many difficulties associated with the use of a completely metallic housing, not the least of which are insulation problems, and the issue of how to attach or mount the female connector portion in such a metallic housing.

Applicants therefore respectfully submit that a person seeking to 15 design an implantable stimulator with a metallic housing, or at least a metallic header, would not start with a conventional arrangement of the type described in Schiff, having a silicone or plastic header, and try to modify it in order to overcome the aforementioned problems which are exclusively related to stimulators having a metallic housing or a metallic header. In fact, the 20 Hawkins et al. reference is evidence of the non-obviousness of Applicants' solution, rather than the obviousness thereof. The Examiner has focused on the Hawkins et al. reference because it discloses using a weld bond to provide a firm attachment of the barrel to the housing, however, claim 10 of the present application requires the use of a metallic *tubular* member having 25 opposite first and second tube ends one of which is attached to an opening in the wall of the housing enclosure. Claim 10 originally stated the tube is "structurally intact" along its entire length. This was intended to mean, and claim 10 now has been amended to explicitly state that the tubular member is *continuous* between the first tube end and the second tube end. This is best 30 seen in Figures 3-6 of the present application wherein it can be seen that the element 21 in the embodiment of Figures 3-5 and the element 21 in the embodiment of Figure 6 each is a "true" tube. Except for the openings 124

and 125, the tube 121 is continuous between the opposite ends, and that tube 21 has no openings. This inventive solution not only overcomes the aforementioned insulation problems, but allows attachment to the metallic housing by means of welding or bonding.

5 The structure disclosed in the Hawkins et al. reference, although making use of welding or bonding, *is not a tube*. As can be seen in Figure 5 of the Hawkins et al. reference, for example, the female socket is composed of a number of successive parts that must be joined together, many of which, such as elements 58 and 60, are insulating. There is no continuous tube
10 disclosed anywhere in the Hawkins et al. reference. There is not even an embodiment in the Hawkins et al. reference that makes use of openings in opposite walls of the metallic housing or header so that the use of a substantially continuous tube would even be meaningful.

This is evidence of the difficulty of arriving at a simplified and operable
15 structure for the female connector socket in the context of the use of a metallic housing or header. It is true that the Schiff reference, as shown in Figure 3, illustrates a structure which could be argued to be a substantially continuous tube, however, it must be remembered that this is in the context of a plastic or silicone header, and the insulating problems which would arise if
20 the structure shown in Figure 3 of the Schiff reference were attempted to be used in a metallic housing or header have already been extensively discussed. Those insulation problems would not disappear if one simply substituted the end portions disclosed in the Hawkins et al. reference for the end portions of the tubular structure shown in Figure 3 of the Schiff reference.
25 This is evidence of the thinking of those of ordinary skill in the art that, if a metallic housing or metallic header is to be used, the assembly for the female socket should not be a continuous tube, but should be composed of separate components joined together, some of which are insulators. This is why one cannot simply begin with a structure intended for use in a silicone or plastic
30 header, and make arbitrary changes therein in accordance with teachings related to female socket assemblies for use with a metallic header, and

assume that the structure used in the plastic or silicone header can otherwise remain unchanged.

The substantially continuous tube disclosed in the Schiff reference can be used only because the header is composed of silicone or plastic. Simply because the Hawkins et al. reference shows how one end of a female socket assembly can be bonded to a metallic housing or header does not mean that, if the Hawkins et al. assembly were somehow embodied in the Schiff assembly, the housing in the Schiff reference could then arbitrarily be made metallic. The aforementioned insulation problem still would not be overcome in such a combination, and there is no teaching in any of the references of record as to how those problems can be solved while still making use of a continuous tubular member in the socket assembly.

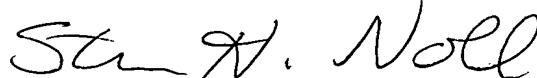
The subject matter of claim 10, therefore, would not have been obvious to a person of ordinary skill in the art based on the teachings of Schiff and Hawkins et al.

Claims 11 and 13-16 were objected to as being dependent on a rejected base claim, but were stated to be allowable if rewritten in independent form. Claims 12 and 17 also were stated to be allowable if rewritten in independent form, as well as if rewritten to overcome the rejections under §112, second paragraph.

In view of Applicants' belief that independent claim 10 is allowable over the art of record for the reasons discussed above, claims 11-17 have been retained in dependent form at this time. All claims of the application are submitted to be in condition for allowance.

25 Early reconsideration of the application is respectfully requested.

Submitted by,



(Reg. 28,982)

SCHIFF, HARDIN & WAITE, CUSTOMER NO. 26574

Patent Department, 6600 Sears Tower

30 233 South Wacker Drive

Chicago, Illinois 60606

Telephone: 312/258-5790

Attorneys for Applicants.